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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,431

09/30/2008

Emmanuel Kossi Tangni

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EXAMINER

HOFFMAN, SUSAN COE

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

05/14/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,431	TANGNI ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/06; 9/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-20 are currently pending.

Election/Restrictions

2. Applicant's election of cereals for species A and wheat for species B in the reply filed on February 25, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.
4. Claims 1-6 and 8-20 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-13, 18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is indefinite because it is unclear what types of foods are encompassed by "food liable to be contaminated with said mycotoxins."
6. Claim 5 is indefinite because due to the use of improper Markush language, it is unclear what elements can be selected as the alternatives.

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7. Claims 12 and 13 are indefinite because they state that the composition is in a form "to be added" to food products at rates from 0.05% to 20% or 0.05% to 10%. The use of "to be added" makes it unclear if applicant is intending to claim a food product with the claimed amounts of the fiber composition or if applicant is only intending to claim that the fiber composition would be capable of being added to food products in the amounts claimed.

8. Claims 13 and 20 are indefinite because it is unclear what characteristics a food must have in order to be considered a "complete" food.

9. Claim 18 is indefinite because it states that the fiber composition can be 100% of the food product. However, claim 1 states that the fiber composition is incorporated into a food product. If the fiber composition represents 100% of the food product, there is no room for the food product that the fiber composition is added to. This conflict between claim 1 and claim 18 makes claim 18 indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 4-6, 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by prior art admitted by applicant in the specification.

On page 9 of the specification, applicant admits that a micronized wheat fiber according to the invention called Realdyme or Realdyme M was known in the art at the time of the

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invention. The specification states that these products are microparticles with 90% by weight of the microparticles less than or equal to 100 micrometers. The specification does not admit that the product is useful for reducing mycotoxin bioavailability or is a food supplement or is in a form to be added to human or animal food. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

11. Claims 1-6, 8, 10-16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Molinie (GB 2 013 077) in light of Chen (Am J Clin Nutr (1998), vol. 68, pp. 711-9) as evidence of inherent characteristics of Molinie.

Molinie teaches finely milled microparticles of wheat bran. 99.4% of the microparticles are less than or equal to 400 microns (see page 1, lines 101-111). The microparticles are added to foods. The reference teaches adding the microparticles to foods in amounts from 1 to 5% of the food. The reference teaches that the foods are for human and animal consumption (see page 2).

Applicant's claims state that the fiber particles are "essentially insoluble." Applicant's specification defines "essentially insoluble" as a composition where the soluble fraction of the fibers does not exceed 55% (see page 7, lines 18-22 of the specification). Molinie does not discuss the content of insoluble fiber in the microparticles. However, as evidenced by Chen, wheat bran contains more than 90% insoluble fiber (see abstract). Thus, the fiber microparticles taught in Molinie would inherently be "essentially insoluble" as claimed by applicant.

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Molinie also does not state that 90% of the particles are between 200 and 2 microns. Moline does teach that 94.3% of the particles are less than or equal to 200 microns but does not measure how many are above 2 microns. According to applicant's specification, plant fibers with the claimed sizes can be made according to the process set forth in FR 2 433 910 (see page 8, lines 6-7). Molinie is in the same patent family as FR 2 433 910 (see Derwent abstract). Thus, it appears that the plant particles in Molinie would be the same size as the claimed microparticles because they are made using the same or similar process as disclosed in the specification.

Molinie does not teach that the product is useful for reducing mycotoxin bioavailability or is a food supplement. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

12. Claims 1-6, 8-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki (JP 05-304915 - translation provided) in light of Chen (Am J Clin Nutr (1998), vol. 68, pp. 711-9) as evidence of inherent characteristics of Suzuki.

Suzuki teaches finely pulverized particles of wheat bran. The reference teaches making particles between 20 and 200 micrometers and gives a specific example where the particles are milled to 80 micrometers. The references teaches incorporating the bran particles in amounts from 3% to 10% of food which can be for human or livestock consumption (see paragraphs 2, 6 and 8 of the translation).

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Applicant's claims state that the fiber particles are "essentially insoluble." Applicant's specification defines "essentially insoluble" as a composition where the soluble fraction of the fibers does not exceed 55% (see page 7, lines 18-22 of the specification). Suzuki does not discuss the content of insoluble fiber in the bran particles. However, as evidenced by Chen, wheat bran contains more than 90% insoluble fiber (see abstract). Thus, the fiber particles taught in Suzuki would inherently be "essentially insoluble" as claimed by applicant.

Suzuki does not teach that the product is useful for reducing mycotoxin bioavailability or is a food supplement. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 10-14 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Molinie.

The teachings of Molinie are discussed above. The reference does not specifically teach adding the microparticles in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill

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in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches that that the microparticles are a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the amount of the microparticles in the composition in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

14. Claims 1, 10-14 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki.

The teachings of Suzuki are discussed above. The reference does not specifically teach adding the microparticles in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches that that the microparticles are a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the amount of the microparticles in the composition in order to formulate a

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product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/

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Primary Examiner, Art Unit 1655